

1
2
3 RECEIVED

4 AUG 23 2005

5 DEPT. OF HEALTH
6 OFFICE OF THE SECRETARY

7 BEFORE THE WASHINGTON STATE DEPARTMENT
8 OF HEALTH

9 In re the Petition for Pilot Project
10 Rule Making of

No.

11 AUBURN REGIONAL MEDICAL
12 CENTER; EVERGREEN HOSPITAL
13 MEDICAL CENTER; GOOD
14 SAMARITAN HOSPITAL; HIGHLINE
15 COMMUNITY HOSPITAL;
16 KENNEWICK GENERAL HOSPITAL;
17 OVERLAKE HOSPITAL MEDICAL
18 CENTER; PEACEHEALTH ST. JOHN
19 MEDICAL CENTER; SKAGIT VALLEY
20 HOSPITAL; ST. CLARE HOSPITAL;
21 ST. FRANCIS HOSPITAL; ST. JOSEPH
22 MEDICAL CENTER; VALLEY
23 MEDICAL CENTER, and YAKIMA
24 VALLEY MEMORIAL HOSPITAL,

PETITION FOR PILOT PROJECT
RULE MAKING

25 Petitioners.

26 INTRODUCTION

COMES NOW Petitioners, Auburn Regional Medical Center, Evergreen Hospital
Medical Center, Good Samaritan Hospital, Highline Community Hospital, Kennewick
General Hospital, Overlake Hospital Medical Center, PeaceHealth, St. John Medical
Center, Skagit Valley Hospital, St. Clare Hospital, St. Francis Hospital, St. Joseph
Medical Center, Valley Medical Center, and Yakima Valley Memorial Hospital, and
pursuant to RCW 34.05.330 and chapter 82-05 WAC, petition the Washington State

PETITION FOR PILOT PROJECT
RULE MAKING

1

KATHLEEN D. BENEDICT, PLLC
1235 Fourth Avenue East, Suite 200
Olympia, Washington 98506
Telephone: (360) 236-9858
Facsimile: (360) 943-4427

1 Department of Health ("Department") to undertake pilot project rule making, in
2 conjunction with a study being conducted by the Johns Hopkins University, to determine
3 whether elective percutaneous cardiac intervention ("PCI") procedures can be performed
4 safely and effectively in hospitals without open heart surgery programs, and, if so,
5 develop appropriate new rules or amendments to chapter 246-310 WAC allowing elective
6 PCI to be performed in such hospitals.

7 **1. Name and Address of Petitioners.**

8 Petitioners include both those hospitals that are currently providing PCI on an
9 emergency basis to patients in their communities but are not authorized to perform
10 elective PCI since they do not have on-site open heart surgery programs and hospital
11 systems with on-site open heart surgery programs that are currently authorized to perform
12 elective PCI. The names and addresses of Petitioners are:

13 Auburn Regional Medical Center
14 Plaza One, 202 N. Division Street
Auburn, WA 98001-4908

15 Evergreen Hospital Medical Center
16 12040 NE 128th Street
Kirkland, WA 98034-9917

17 Good Samaritan Hospital
18 407 14th Avenue SE
Puyallup, WA 98372-0118

19 Highline Community Hospital
20 16251 Sylvester Road SW
Burien, WA 98166-0657

21 Kennewick General Hospital
22 900 S. Auburn
Kennewick, WA 99336-6128

23 Overlake Hospital Medical Center
24 1035 - 116th Avenue NE
Bellevue, WA 98004

25 PeaceHealth, St. John Medical Center
26 1615 Delaware Street
Longview, WA 98632-3002

- 1 Skagit Valley Hospital
1415 E. Kincaid Street
2 Mount Vernon, WA 98273-1376
- 3 St. Clare Hospital
11315 Bridgeport Way SW
4 Lakewood, WA 98499
- 5 St. Francis Hospital
34515 Ninth Ave. S.
6 Federal Way, WA 98003
- 7 St. Joseph Medical Center
1717 South J Street
8 Tacoma, WA 98405
- 9 Valley Medical Center
400 S. 43rd Street
10 Renton, WA 98058-5010
- 11 Yakima Valley Memorial Hospital
2811 Tieton Drive
12 Yakima, WA 98902

13 **2. Name and Address of Agency Responsible for Administering the Rule.**

14 Washington State Department of Health
Point Plaza East
15 310 Israel Road SE
P. O. Box 47850
16 Olympia, WA 98504-7850

17 The Department is the state agency authorized and directed to implement the
18 Health Planning and Development Act, chapter 70.38 RCW (the "Act") in the state of
19 Washington. The purpose of the Act is to ensure health services and resources are
20 developed in this state in a planned, orderly fashion, consistent with identified priorities
21 and without unnecessary duplication. RCW 70.38.015. The Act also states as a goal that
22 health planning should promote, maintain, and assure the health of all citizens in the
23 state, and provide accessible health services, health manpower, health facilities, and other
24 resources while controlling excessive increases in costs. *Id.* The Department has
25 adopted the rules set forth in chapter 246-310 WAC to assist it in implementing the Act.
26

1 3. **Rationale for Pilot Rule Making Project and Subsequent Rule Adoption,**
2 **Amendment or Repeal.**

3 Under RCW 34.05.330, any person may petition an agency to request the
4 adoption, amendment, or repeal of a rule. The Administrative Procedure Act's
5 ("APA's") rule adoption procedures include pilot rule making projects. RCW 34.05.310,
6 .313. Petitioners submit this Petition for Pilot Project Rule Making to the Department to
7 determine whether the Department's rules should be amended or augmented to allow
8 hospitals without on-site open heart surgery programs to perform elective PCI procedures
9 and, if so, to develop such rules. See WAC 246-310-010, -020, -261, and -262. This
10 petition is necessary because Washington has the unique time sensitive opportunity to
11 participate in a nationwide study being conducted by Johns Hopkins University (the
12 "Johns Hopkins Study" or "Study") to gather scientific data to address several issues that
13 have been debated within this state for a number of years:

- 14 ○ *Can elective PCI procedures (angioplasty) be performed safely and*
15 *effectively at hospitals without an on-site open heart surgery program;*
16 *and*
17 ○ *If so, under what conditions and circumstances is this possible?*

18 Currently, the certificate of need (CON) rules only allow elective PCI procedures
19 to be performed only in hospitals with on-site heart surgery programs. Technological
20 advances have resulted in dramatically reducing the risks associated with elective PCI
21 which has called into question whether the requirement for an on-site open heart surgery
22 program is still necessary. Notably, in Washington, hospitals without on-site open heart
23 surgery programs are currently allowed to perform PCI procedures on an emergency
24 basis. These hospitals have performed emergency PCI procedures for over a decade with
25 exemplary outcomes. In fact, the Department's data identifies almost 900 emergency
26

1 PCI procedures were performed in hospitals without on-site open heart surgery programs
2 in 2004. Moreover, elective PCIs are regularly performed in many hospitals across the
3 nation and in other countries as well.

4 In the spring of 2000, the Legislature unanimously passed HB 3005 requiring the
5 Department to establish an advisory committee (the Heart Surgery Advisory Committee)
6 to create a new CON methodology for PCI procedures and promptly adopt the revised
7 methodology into rule. The Heart Surgery Advisory Committee was comprised of some
8 of this State's best cardiologists, cardiac surgeons, hospital administrators, and other
9 technical experts. In the summer of 2001, the Heart Surgery Advisory Committee
10 published recommendations that allowed hospitals without on-site open heart surgery
11 programs to perform elective PCI procedures if the hospital met specific CON standards
12 and criteria. Shortly thereafter, the Department commenced rule making based on the
13 recommendations of the Advisory Committee.

14 Despite several years and numerous public rule hearings, the rules have not been
15 adopted. The opponents to the rules have based their opposition on whether enough
16 quality data exists to ensure the safety and feasibility of the proposed elective PCI rule
17 change. In the spring of 2005, the Department withdrew its proposed rules until such
18 time as further data was available.

19 Johns Hopkins University is the leading medical research center in the country. It
20 is now conducting a nationwide comprehensive research study, funded in part through
21 participating sites, which allows hospitals without on-site open heart surgery programs
22 that meet specific participation criteria (e.g., facility and operator volume requirements)
23 to perform elective PCI procedures within a randomized trial format. Johns Hopkins
24
25
26

1 would like to include Washington State hospitals in the Study. The Study will provide
2 the quality data the Department asserts it needs to finally determine the safety and
3 feasibility of performing elective PCI in hospitals without on-site open heart surgery
4 programs. Thus, the Study offers Washington the perfect opportunity to pilot the concept
5 of removing the requirement of an on-site open heart surgery program for elective PCI
6 procedures, with the necessary programmatic and research controls to ensure patient
7 safety. There are no downsides to undertaking this pilot rule making project in
8 conjunction with the Johns Hopkins Study and having our state-specific data included in
9 this important national research project.
10

11 **4. The Requested Proposed Pilot Rule Making Project.**

12 As stated, this pilot rule making project is necessary to determine whether such a
13 rule change allowing CONs for elective PCI procedures in hospitals that do not have on-
14 site open heart surgery programs is feasible and furthers the goals and purposes of the
15 Health Planning and Development Act, chapter 70.38 RCW. Petitioners therefore ask the
16 Department to conduct a pilot rule making project in conjunction with the Johns Hopkins
17 Study's nationwide research study project to examine the feasibility of performing
18 elective PCI procedures in hospitals without on-site open heart surgery programs and,
19 based on that research, if appropriate, develop elective PCI rules. Johns Hopkins
20 University has established criteria for participating hospitals, clearly defined measurable
21 outcomes, and is committed to working closely with approved hospitals in program
22 development, and with the Department to develop any state specific criteria necessary to
23 allow participation. The Johns Hopkins Study also includes a data and safety monitoring
24 (quality assurance) board (referred to as the "DSMB") to monitor the outcomes and to
25 address any concerns. Notably, the Johns Hopkins Study criteria for participating
26

1 hospitals closely mirrors the recommendations of the Heart Surgery Advisory
2 Committee, as well as the Department's earlier proposed elective PCI rules.

3 Although Johns Hopkins University will determine which hospitals meet the
4 Study's participation criteria, the Department would retain final decision making on
5 which hospitals would participate as volunteers in the Department's pilot rule making
6 project. Throughout the course of the pilot project and Johns Hopkins Study, the
7 Department would have immediate and ongoing access to the Study data and outcomes in
8 order to monitor the results. The Department would be able to terminate the pilot rule
9 making project, and its participation in the Johns Hopkins Study, at any time it
10 determined patient safety was at risk. The Department would also retain the final
11 decision-making authority regarding any subsequently proposed rule amendments, new
12 rule provisions, or other changes the Department may pursue in accordance with the
13 APA's rule making provisions. *See* RCW 34.05.310 - .395.

14 a. **Authority for the Proposed Pilot Rule Making Project.**

15 The APA, chapter 34.05 RCW, gives the Department the authority and framework
16 to participate in pilot rule making projects and feasibility studies like the Johns Hopkins
17 Study. *See* RCW 34.05.310, .313, .325. Not only does the APA specifically authorize
18 pilot rule making projects and feasibility studies, it actively encourages such study
19 projects under RCW 34.05.310 and RCW 34.05.313. First, RCW 34.04.310 states:

20
21 (2) Agencies are encouraged to develop and use new procedures for
22 reaching agreement among interested parties before publication of notice
23 and the adoption hearing on a proposed rule. Examples of new procedures
include, but are not limited to:

24 (b) Pilot rule making which includes testing the feasibility of complying
25 with or administering draft new rules or draft amendments to existing
26 rules through the use of volunteer pilot groups in various areas and
circumstances, as provided in RCW 34.05.313 or as otherwise provided by
the agency.

1 RCW 34.05.310(2)(b).

2
3 The section is then followed by the specific provisions of RCW 34.05.313 which,
4 in relevant part, state:

5 (1) During the development of a rule or after its adoption,¹ an agency may
6 develop methods for measuring or testing the feasibility of complying with
7 or administering the rule and for identifying simple, efficient, and
8 economical alternatives for achieving the goal of the rule. A pilot project
9 shall include public notice, participation by volunteers who are or will be
10 subject to the rule, a high level of involvement from agency management,
11 reasonable completion dates, and a process by which one or more parties
12 may withdraw from the process or the process may be terminated.
13 Volunteers who agree to test a rule and attempt to meet the requirements
14 of the draft rule, to report periodically to the proposing agency on the
15 extent of their ability to meet the requirements of the draft rule, and to
16 make recommendations for improving the draft rule shall not be obligated
17 to comply fully with the rule being tested nor be subject to any
18 enforcement action or other sanction for failing to comply with the
19 requirements of the draft rule.

20 (2) An agency conducting a pilot rule project authorized under subsection
21 (1) of this section may waive one or more provisions of agency rules
22 otherwise applicable to participants in such a pilot project if the agency
23 first determines that such a waiver is in the public interest and necessary to
24 conduct the project. Such a waiver may be only for a stated period of
25 time, not to exceed the duration of the project.

26 (3) The findings of the pilot project should be widely shared and, where
appropriate, adopted as amendments to the rule.

23
24 ¹ The Legislature's solution to adversarial rule making was to authorize and encourage agencies to undertake pilot
25 projects, after adoption of the rule, to determine the feasibility of the rule as applied. Chapter 202, Laws of 1993
26 (RCW 34.05.310). This section was re-written in 1994 (chapter 249, §1, Laws of 1994) and in 1995 as part of the
Regulatory Reform Act (chapter 403, §301, Laws of 1995). Under these latter amendments, the Legislature granted
agencies the authority to undertake pilot rule making projects during the development of the rule as well as after
adoption. RCW 34.05.313(1).

1 (Emphasis added). The Department is further authorized, under RCW 70.38.135, to use
2 the services of expert and consultant organizations, like Johns Hopkins, on a part time,
3 intermittent, or temporary basis.

4 Notably, under RCW 34.05.313(2), the Department is allowed to waive one or
5 more provisions of the Department's existing CON rules that would otherwise be
6 applicable to volunteers participating in the pilot rule making project, if the waiver is (1)
7 in the public interest, and (2) necessary to conduct the project. For purposes of this
8 proposed pilot project, it is without question in the "public's interest" to determine
9 whether elective PCI procedures can safely be performed in hospitals without on-site
10 open heart surgery programs. If, as a result of the pilot rule making project and Johns
11 Hopkins Study, the Department concludes that elective PCI procedures in hospitals
12 without on-site open heart surgery programs can be performed safely and effectively, and
13 that accordingly, appropriate amendments or new rules should be included in chapter
14 246-310 WAC, the public would benefit by:
15

- 16 ○ increasing patient and family access, choice, and satisfaction when
17 services are provided closer to home;
- 18 ○ reducing costs (by avoiding transfer to other facilities with on-site heart
19 surgery services and potential additional hospital days),
- 20 ○ reducing unnecessary complications caused by additional tests and
21 procedures, and patient transfers;
- 22 ○ improving the ability of communities to recruit and retain cardiologists;
- 23 and
- 24
- 25
- 26

- improving the ability of communities to sustain emergency life-saving PCI programs at hospitals without on-site open heart surgery programs.

With regard to the second waiver criteria, it would be necessary to the conduct of the project to waive the current percutaneous transluminal coronary angioplasty ("PTCA") rule (for the volunteers) since volunteers performing PCIs without an open heart surgery CON would otherwise be out of compliance with the CON rules.² See RCW 34.05.313(2). The Department accordingly meets both prongs of RCW 34.05.313(2) to grant a time-limited waiver of the current open heart and PTCA rules to qualified "volunteer" hospitals that would facilitate these hospitals' participation in the pilot rule making project and Johns Hopkins Study.³ See WAC 246-310-261, -262.

Petitioners therefore further request that the Department waive the current PTCA rule set forth in WAC 246-310-262, which states:

WAC 246-310-262 Nonemergent interventional cardiology standard.
All nonemergent percutaneous transluminal coronary angioplasty (PTCA) procedures and all other nonemergent interventional cardiology procedures are tertiary services as defined in WAC 246-310-010 and shall be performed in institutions which have an established on-site open heart surgery program capable of performing emergency open heart surgery.

If the Department were to waive this rule for the pilot project volunteers, PTCA would not be considered a "tertiary service" that could only be performed in a hospital with a

² The waiver(s) would only be granted for the duration of the pilot rule making project/Johns Hopkins Study.

³ The pilot project rule making provisions included in RCW 34.05.313 actually contain two waiver provisions. The first provision allows the Department to waive one or more provisions of the proposed rules during the course of the pilot project so that volunteers would not be subject to an enforcement action or other sanction for failing to comply with the requirements of the proposed rule criteria. RCW 34.05.313(1). The second provision allows the Department to waive provisions of the agency's current open heart surgery and PTCA rules that would otherwise be applicable to the volunteers participating in the pilot project, as long as a waiver was in the public interest and necessary to the conduct of the project. RCW 34.05.313(2).

1 CON approved open heart surgery program.⁴ *Id.*; see also WAC 246-310-261.
2 Additionally, even with the waiver of this rule for the pilot project volunteers, the open
3 heart surgery rule would remain in effect and the volunteers (or any other hospitals)
4 would still be required to obtain a CON if they intended to perform open heart surgeries,
5 or establish an open heart surgery program. See WAC 246-310-261. Lastly, the PTCA
6 rule would remain in effect and not be waived for those hospitals not participating in the
7 pilot rule making project and Johns Hopkins Study.
8

9 **b. The Department's Incorporation of the Johns Hopkins Study Into the**
10 **Pilot Rule Making Project Would Allow the Department to Easily**
11 **Comply with the Provisions of RCW 34.05.313.**

12 A pilot rule making project undertaken in conjunction with the Johns Hopkins
13 Study also requires the Department to comply with the requirements of RCW
14 34.05.313(1). Thus, to meet these requirements, Petitioners request the Department:

15 (1) allow any hospital qualified⁵ to participate in the Johns Hopkins
16 Study to participate in the pilot rule making project;

17 (2) assign upper management level staff to monitor the pilot rule
18 making project, the Johns Hopkins Study, and the data produced by the Study;

19 (3) establish a three-year completion date for the pilot rule making
20 project and Johns Hopkins Study, and establish a process for extending the date if
21 additional research and data is necessary;
22

23 ⁴ WAC 246-310-010 and WAC 246-310-020 currently define "tertiary service" to include PTCA as part of open heart
24 surgery tertiary services. These rule definitions should also be waived for volunteer hospitals.

25 ⁵ The Johns Hopkins Study has developed qualifications and criteria for participating hospitals. In addition, the state
26 will have the ability to develop state-specific criteria addressing issues such as the impact on existing providers. For
example, Georgia's (one of the participating states) key criterion specified that a participating hospital would not
reduce an existing hospital's PTCA program below an optimum level.

1 (4) establish a process by which a volunteer can withdraw or be
2 terminated from the pilot rule making project and/or the Johns Hopkins Study, or
3 terminate the Department's participation in the Johns Hopkins Study entirely;

4 (5) adopt and access the elective PCI criteria and protocols of the
5 Johns Hopkins Study as part of the pilot rule making project;

6 (6) fully avail itself of the experts associated with the Johns Hopkins
7 Study, as authorized by RCW 70.38.135;

8 (7) exercise its authority under RCW 34.05.313(2) to waive the
9 provisions of WAC 246-310-262, and, if necessary, other provisions of the Department's
10 existing CON rules, so that volunteer hospitals can fully participate in the pilot rule
11 making project;

12 (8) following the completion of the pilot rule making project and
13 Johns Hopkins Study, assess the outcomes and either propose changes and/or additions to
14 the Department's existing open heart surgery and PTCA rules, or issue a determination
15 that it will not adopt any elective PCI rules, with the reasons for its decision (RCW
16 34.05.313(3)); and

17 As stated, the Johns Hopkins Study also has established its DSMB (data and
18 safety monitoring board) to monitor data, safety issues, and outcomes to quickly address
19 any concerns. Petitioners therefore further request the Department adopt the Johns
20 Hopkins Study DSMB to assist with its monitoring and oversight responsibilities.

1 c. **The Pilot Rule Making Project, in Conjunction with the Johns**
2 **Hopkins Study, will Provide the Necessary Data to Determine**
3 **Whether the Adoption of Elective PCI Rules is Feasible.**

4 At the end of the Johns Hopkins Study and pilot rule making project, Johns
5 Hopkins will provide the Department (and the other participating states) a report of the
6 Study's findings ("Report"). The Johns Hopkins Study Report will directly address the
7 concerns raised in the Department's prior heart surgery rule making proceedings. If the
8 Report concludes that elective PCI procedures can be safely and effectively performed in
9 hospitals without on-site open heart surgery programs, the Department would have a
10 solid foundation upon which to build a new elective PCI rule making proposal.

11 5. **Other Concerns to be Addressed in Accordance with RCW 34.05.330(4).**

12 As encouraged under RCW 34.05.330(4), Petitioners address the following
13 additional potential concerns:

14 (a) As discussed in the Petition's header/paragraph 4(a) above, the APA
15 clearly authorizes the Department to undertake a pilot rule making project in conjunction
16 with the Johns Hopkins Study.

17 (b) As discussed in the Petition's header/paragraph 3 above, the proposed
18 pilot rule making project, in conjunction with the Johns Hopkins Study, is needed to
19 determine whether elective PCI procedures can be safely and effectively performed in
20 hospitals without on-site open heart surgery programs, and to develop proposed rules
21 that, depending on the results of the Study, the Department may adopt as amendments or
22 additional rules under chapter 246-310 WAC.

23 (c) The proposed pilot rule making project, in conjunction with the Johns
24 Hopkins study, will not conflict with or duplicate federal, state, or local law.

25 (d) No better alternatives to the pilot rule making project exist.
26

(e) There are no less costly alternatives to the proposed pilot rule making project undertaken in conjunction with the Johns Hopkins Study.

(f) The proposed pilot rule making project, and any subsequent rule changes that are undertaken as a result of the project, would impact and apply equally to public and private entities.

(g) If the proposed pilot rule making project results in the adoption of rules allowing elective PCI procedures to be performed in hospitals without on-site open heart surgery programs, such rules will not impose unreasonable costs on patients, hospitals, or other health care providers.

(h) The proposed pilot rule making project could develop an elective PCI rule that is clearly and simply stated.

(i) Petitioners firmly believe the Department can undertake the pilot rule making project, in conjunction with the Johns Hopkins Study, and adopt any resulting rules, in accordance with all applicable laws.

WHEREFORE, Petitioners petition and request the Department to commence a pilot rule making project, in conjunction with the Johns Hopkins Study, to (1) determine whether elective PCI procedures can be performed safely and effectively in hospitals without on-site open heart surgery programs; (2) during the course of the pilot project begin the development of rules as appropriate⁶; and (3) if appropriate from the findings of the pilot project, amend and/or augment chapter 246-310 WAC⁷ to allow CONs to be

⁶ As stated in RCW 34.05.313(1), agencies may also undertake pilot rule making projects to develop rules. In relevant part, RCW 34.05.313(1) states:

During the development of a rule or after its adoption, an agency may develop methods for measuring or testing the feasibility of complying with or administering the rule and for identifying simple, efficient, and economical alternatives for achieving the goal of the rule.

(Emphasis added.) Petitioners are asking the Department to pursue the first option of using the pilot rule making project to not only conduct a feasibility study, but as the feasibility study proceeds, to also work toward the development of rules that may ultimately be appropriate for adoption. Petitioners are not asking the Department to follow the second option of adopting a rule and then testing the feasibility study of that rule.

⁷ Pursuant to RCW 34.05.313(3), the findings of the pilot rule making project are required to be widely shared "and, where appropriate, adopted as amendments to the rule."

1 issued to qualified applicants for the establishment of elective PCI programs without the
2 requirement of on-site heart surgery programs, define elective PCI as a tertiary service
3 separate and apart from open heart surgery tertiary services, and develop clear,
4 understandable, and consistent new rule requirements for the issuance of a CON for
5 elective PCI programs.

6 DATED this 23rd day of August, 2005.

7 KATHLEEN D. BENEDICT, PLLC
8

9 By: Kathleen D. Benedict
10 Kathleen D. Benedict, WSBA #07763
11 Attorneys for Petitioners
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26